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Rockville, Maryland 20857
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

[DOCKET NO. 85D-0242] 85D-0249

DRAFT GUIDELINES SUPPLEMENTING THE REGULATIONS GOVERNING THE REVIEW AND APPROVAL OF NEW DRUG AND ANTIBIOTIC MARKETING APPLICATIONS

9-24-85

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of nine draft guidelines to supplement the recently published final regulations governing the review and approval of new drug and antibiotic marketing applications. The guidelines are intended to assist applicants in complying with the requirements of the regulations. FDA is making these guidelines available in draft to solicit public comments on them. FDA is also making available a staff manual guide on time frames applicable to the review and approval of marketing applications. The draft guidelines and the staff manual guide were prepared by FDA's Center for Drugs and Biologics.

DATE: Comments by (insert date 90 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Requests for copies of the draft guidelines may be made in writing to the Support Services Branch (HFN-62), Center for Drugs and Biologics, Food and Drug Administration, Rm. 13B-05, 5600 Fishers Lane, Rockville, MD 20857, or by telephone to 301-443-6060. A request for a guideline should identify the desired guideline by its docket number. A request for the staff manual guide on time frames should request it by its number, CDB

Written comments regarding the draft guidelines may be submitted to the Dockets Managment Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Comments on a draft guideline should identify the guideline by its title and docket number.

FOR FURTHER INFORMATION CONTACT:

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5600 Fishers Lane,
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301-443-5220.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of February 22, 1985 (50 FR 7452), FDA revised the regulations governing the approval for marketing of new drugs and antibiotic drugs for human use. This rule--otherwise known as the NDA Rewrite--was intended to speed up the availability of beneficial drugs to consumers by improving the efficiency of the agency's approval process for new drugs and antibiotic drugs while improving the high level of public health protection the previous procedures already provided. The NDA Rewrite was designed to assist drug manufacturers to prepare and submit higher quality applications and permit FDA to review them more efficiently and with fewer delays.

In the NDA Rewrite final regulations, FDA stated its intent to supplement the regulations with detailed guidelines intended to provide applicants with guidance on application format and

presentation and on other provisions of the regulations. In this notice, FDA is announcing the availability in draft of the following nine new guidelines:

1. Guideline for the Format and Content of an Application Summary [Docket No. 85D-0247].

2. Guideline for the Format and Content of the Chemistry, Manufacturing, and Controls Section of an Application [Docket No. 85D-0243].

3. Guideline for the Format and Content of the Nonclinical Pharmacology/Toxicology Section of an Application [Docket No. 85D-0244].

4. Guideline for the Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application [Docket No. 85D-0275].

5. Guideline for the Format and Content of the Microbiology Section of an Application [Docket No. 85D-0245].

6. Guideline for the Format and Content of the Statistical Section of an Application [Docket No. 85D-0246].

7. Guideline on Formatting, Assembling, and Submitting New Drug and Antibiotic Applications [Docket No. 85D-0248].

8. Submission in Microfiche of the Archival Copy of an Application [Docket No. 85D-0250].

9. Guideline for Postmarketing Reporting of Adverse Drug Reactions [Docket No. 85D-0249].

The draft guidelines on the presentation and format of the application suggest appropriate ways to organize and present the required data and information in the application summary and in the technical sections of the application--the sections on chemistry, manufacturing, and controls; nonclinical pharmacology/ toxicology; biopharmaceutics and bioavailability; microbiology; and statistics. In addition, FDA will shortly be making available a presentation and format guideline for the clinical section of the marketing application. The availability of this one additional draft guideline will also be announced in a notice to be published in the FEDERAL REGISTER.

The draft guideline "Guideline on Formatting, Assembling, and Submitting New Drug and Antibiotic Applications" provides general guidance to applicants on the mechanics of putting together the archival and review copies of an application. This guidance includes recommendations on how to organize multivolume submissions. This guideline also identifies appropriate agency offices to which applications and correspondence should be sent.

The draft guideline "Submission In Microfiche of the Archival Copy of an Application" suggests procedures and specifications to be followed when an applicant chooses to submit the archival copy of an application in microfiche.

Finally, the draft guideline "Guideline for Postmarketing Reporting of Adverse Drug Reactions" provides guidance for complying with the requirements for reporting adverse drug reactions in 21 CFR 314.80. This guidance includes information on completing the Form FDA-1639, on the sources of adverse drug reaction information, and on how to submit the reports.

In conjunction with publication of these guidelines, FDA is also making available a staff manual guide (Guide CDB 4820.2.1) on time frames governing the review and approval of applications for new drugs and antibiotics. This document describes the review and filing clocks that govern agency review of pending applications. It also provides guidance for determining whether an amendment to a pending application is sufficiently "major" to justify extending the date by which the agency is required to act on an application, and, if so, what the length of the extension should be. Under § 314.60 of the NDA Rewrite, submission of a "major" amendment, whether on the applicant's own initiative or at the agency's request, constitutes an agreement to extend the review period for the time estimated to be necessary to review the new information. This new staff manual guide may be obtained from the Support Services Branch, address above.

Section 10.90(b) provides for the use of guidelines to establish procedures of general applicability that are not legal requirements but are acceptable to the agency. A person who follows a guideline can be assured that his or her conduct will be acceptable to the agency. A person may choose to use alternative procedures even though they are not provided for in the guideline. A person who chooses to do so may discuss the matter further with the agency to prevent an expenditure of money and effort for work that the agency may later determine to be unacceptable. Therefore, interested persons are encouraged to use this opportunity to submit comments on the draft guidelines if they have suggestions for their revision.

Interested persons may, on or before (insert date 90 days after date of publication in the FEDERAL REGISTER), submit written comments on the draft guidelines to the Dockets Management Branch (address above). These comments will be considered in determining whether amendments to, or revisions of, the draft guidelines are warranted. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets next to the title of each draft guideline listed above. The draft guidelines and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 19, 1985.

JUN 19 1985

Frank E. Young
Commissioner of
Food and Drugs

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